Remarks/Arguments:

Introduction

Claims 1-9, 11-15, 17-24, 27-31, 33-37 and 41-45 are pending. Claim 41 is withdrawn from consideration as allegedly being directed to a non-elected invention. Claims 42-45 have been added.

Claim 1 has been amended and claim 43 has been added to further describe that the wires along the length of the prosthesis, including the area of curvature, have a constant pitch. Claim 23 has been amended and claims 42-45 have been added to further describe that the wires have an increased pitch at the outside segment and have a reduced pitch at the inside segment when disposed on a straight mandrel, i.e., when the curved portion of the stent, which has a uniform and equal distribution of wires in the curved state, is straightened, the wires no longer have a constant and equal distribution. Support for these amendments may be found in the Specification, as follows:

> **In the case of the anatomically correct stent, [the stent] has an equal distribution of wires and turns [i.e., pitch] along the length of the stent .... [A]n unequal distribution of wire [may be used] to form the desired curvature....** (Specification, page 20, first full paragraph, lines 1-11) **Using a large pitch on one side of the stent and smaller on the other would creates an area of curvature . ... Areas of less pitch 164 represent the eventual inside of the curve to be fabricated, while areas of increased pitch 166 correspond to the outside of the curve. ... [T]he stent ... would bend naturally [after being removed from a straight mandrel] into the curvature imposed by the unequal distribution of wire around the stent, [i.e., by] letting the [wire] wrappings slip to the correct positions.** (Specification, page 20, last paragraph, line 6, to page 21, line 4)

In summary, the invention as presently defined by independent claim 1 is an endoluminal prosthesis comprising a proximal end, a distal end and a hollow tubular body comprising a stent scaffold, the stent scaffold consisting essentially of wires having turns; the hollow tubular body comprising at least one segment of curvature; the segment of curvature

comprising an inside of the curvature and an outside of the curvature; wherein the wires and their turns are distributed substantially equally and uniformly displaced along the length of the prosthesis, including being distributed substantially equally and uniformly displaced along the length of the segment of curvature, to provide a constant pitch of the wires therealong. (emphasis added)

Further, the invention as presently defined by independent claim 23 is an endoluminal prosthesis comprising a proximal end, a distal end and a hollow tubular body comprising a stent scaffold consisting essentially of wires having turns; the hollow tubular body comprising at least one segment of curvature; the segment of curvature comprising an inside of the curvature and an outside of the curvature; wherein the wires and their turns are distributed substantially equally and uniformly displaced along the length of the prosthesis, including being distributed substantially equally and uniformly displaced along the length of the segment of curvature; wherein the wires have an increased pitch at the outside segment and have an reduced pitch at the inside segment when disposed on a straight mandrel; and further wherein the hollow tubular body is geometrically shaped and sized to approximate an anatomical shape. (emphasis added)

Section 102 Rejections

Claims 1, 2, 4, 8, 9, 11, 15, 16, 17, 22, 23, 24, 27, 31, 32 and 33 are rejected under 35 U.S.C. §102(e) as allegedly being anticipated by U.S. Patent No. 6,027,525 to Suh et al. (hereinafter "Suh"). In particular, the examiner alleges that:

> **Suh discloses an endoluminal prosthesis comprising a proximal end, a distal end, and a hollow tubular body comprising a stent scaffold (elastic units 1) consisting essentially of wires of a shape memory material (Column 1 lines 15-23, Column 4 lines 21-24), having turns (FIGS. 1 and 2); the hollow tubular body comprising at least one segment of curvature (FIG. 2) to approximate an anatomical shape of the anatomical site intended for placement of the prosthesis**

> **(Column 4 lines 33-41); the segment of curvature comprising an inside of the curvature and an outside of the curvature; wherein the wires and their turns are distributed substantially equally along the length of the prosthesis (FIG. 2 units 1), including being distributed substantially equally along the length of the segment of curvature; wherein the hollow tubular body comprises a thin-walled tube material (member 3, also considered to be a graft material) wherein the center of the thin-walled tube provides the center of the prosthesis.** (Office Action dated January 24, 2006, pages 2-3) (emphasis added)

Applicant respectfully traverses because Suh fails to disclose, *inter alia*, a scaffold consisting essentially of wires having where the wires and their turns are distributed substantially equally and uniformly displaced along the length of the prosthesis, including being distributed substantially equally and uniformly displaced along the length of the segment of curvature. In particular, as emphasized above, the action has failed to provide any citation to Suh for the necessary claim limitation that the stent wires of Suh be distributed substantially equally and uniformly displaced along the length of the segment of curvature of the stent.

Indeed, Suh specifically discloses that its stent wires are not distributed substantially equally and uniformly displaced along the length of the segment of curvature of the stent, as follows:

> **As shown in FIG. 2 [which is reproduced below for the convenience of the Examiner], when the stent according to the present invention is placed in a lumen, the stent is gently curved corresponding to the curvature of the same.**
>
> **The above is possible because the distance between adjacent upper and lower bends 10 and 10' of each unit 1 at an outer portion of the stent (with respect to the curving direction) enlarges, while the distance between the adjacent upper and lower bends 10 and 10' of each elastic unit 1 at an inner portion of the stent (with respect to the curving direction) decreases. As a result, the stent can be gently curved as shown in FIG. 2.** (Suh, column 4, lines 38-48) (emphasis added)

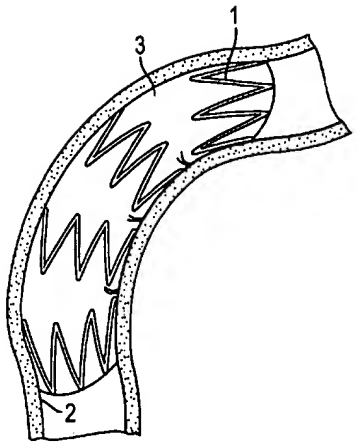

FIG. 2

Thus, Suh specifically discloses that its stent wires are not equally spaced along the length of the segment of curvature of its stent. Moreover, Suh specifically states that curvature of its stent is only possible when the wires at one portion are moved to a different degree than the wires at another portion of the curvature.

Moreover, the examiner acknowledges that the wire turns of Sun are not evenly distributed, as follows:

> **From FIGS. 1 and 2 of Suh...[t]he turns are spaced further apart on the outer edge of the curve and are closer together on the inner edge of the curve.** (Office Action dated January 24, 2006, page 5)

As such, in direct contrast to the limitations of independent claim 1, the wires of Suh do not have a constant pitch[1] at its curved portions of the stent.

Thus, Suh fails to disclose the invention as presently defined by independent claim 1. Reconsideration and withdrawal of the rejections of claims 1 and all claims dependent therefrom are respectfully requested.

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[1] Pitch 9b.: The distance between two corresponding points on a helix. THE AMERICAN HERITAGE COLLEGE DICTIONARY, 1042 (3d ed. 1997);

Moreover, with respect to independent claim 23, the "curved" stent of Shu, i.e. FIG. 1 of Shu above, is not described as having increased pitch and decreased pitch when disposed on a straight mandrel or otherwise longitudinally straightened, as depicted in FIG. 2 of Shu, as follows:

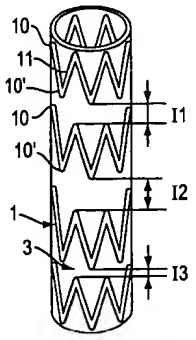


FIG. 1

Thus, Suh fails to disclose the invention as presently defined by independent claim 23. Reconsideration and withdrawal of the rejections of claim 23 and all claims dependent therefrom are respectfully requested.

Therefore reconsideration and withdrawal of the rejections of claims 1, 2, 4, 8, 9, 11, 15, 16, 17, 22, 23, 24, 27, 31, 32 and 33 under 35 U.S.C. §102(e) are respectfully requested.

Section 103 Rejections

Claims 3, 5, 6, 7, 17 and 33 are rejected under 35 U.S.C. §103(a) as allegedly being obvious over Suh in view of WO 95/09585 (hereinafter "Caro"). Claims 12-14, 28, 29 and 30 are rejected under 35 U.S.C. §103(a) as allegedly being obvious over Suh in view of U.S. Patent No. 4,994,071 to MacGregor (hereinafter "MacGregor"). Claims 18 and 34 are rejected under 35 U.S.C. §103(a) as allegedly being obvious over Suh in view of U.S. Patent No. 5,653,743 to Martin (hereinafter "Martin"). Claims 19, 21, 35 and 37 are rejected under 35

U.S.C. §103(a) as allegedly being obvious over Suh in view of U.S. Patent No. 6,325,826 to Vardi et al. (hereinafter "Vardi"). Claims 20 and 36 are rejected under 35 U.S.C. §103(a) as allegedly being obvious over Suh in view of U.S. Patent No. 5,695,517 to Marin et al. (hereinafter "Marin"). Applicant respectfully traverses.

Suh in view of Caro:

As discussed above, Suh fails to teach or suggest a stent scaffold having a segment of curvature where stent wires are substantially equally and uniformly distributed along the length of the segment of curvature of the stent to provide a constant pitch of wires therealong, and fails to teach or suggest a stent scaffold having a segment of curvature where stent wires are substantially equally and uniformly distributed along the length of the segment of curvature of the stent and where the wires have an increased pitch at the outside segment and have an reduced pitch at the inside segment when disposed on a straight mandrel. Further, Suh teaches away from the present invention as Suh specifically states that curvature of its stent is only possible through unequal distribution of its stent wires in the curved state. (See Suh, column 4, lines 38-48 as presented above).

Caro, however, fails to cure the deficiencies of Suh. Caro discloses a three-dimensionally curved prosthesis. (See e.g., Caro, Fig. 5). The prosthesis includes a tube of bio-compatible material held open by a stent. (Caro, page 6, lines 4-9). Caro, however, fails to teach or suggest any stent details, including details of stent wire distribution and/or configuration. Thus, Caro fails to cure the above-discussed deficiencies of Suh.

Thus, Suh and Caro, individually or in combination, fail to teach or suggest the present invention.

Therefore, reconsideration and withdrawal of the rejections of claims 3, 5, 6, 7, 17 and 33 under 35 U.S.C. §103(a) are respectfully requested.

Suh in view of MacGregor:

As discussed above, Suh fails to teach or suggest a stent scaffold having a segment of curvature where stent wires are substantially equally and uniformly distributed along the length of the segment of curvature of the stent to provide a constant pitch of wires therealong, and fails to teach or suggest a stent scaffold having a segment of curvature where stent wires are substantially equally and uniformly distributed along the length of the segment of curvature of the stent and where the wires have an increased pitch at the outside segment and have an reduced pitch at the inside segment when disposed on a straight mandrel. Further, Suh teaches away from the present invention as Suh specifically states that curvature of its stent is only possible through unequal distribution of its stent wires in the curved state. (See Suh, column 4, lines 38-48 as presented above).

MacGregor, however, fails to cure the deficiencies of Suh. MacGregor describes a bifurcated stent 10 having a main tubular body or lattice 16 and two tubular legs or lattices 20, 23. (MacGregor, column 3, lines 54-68, Fig. 1). The lattices 16, 20, and 22 have a series of loops 12, 12'', 12', respectively, which are depicted as undulating looped wires. (*Id.*) A longitudinally extending wire 24 interconnects loops 12 and 12' and further interconnects lattices 10 and 22. (MacGregor, column 4, lines 1-4). A second longitudinally extending wire 26 similarly interconnects loops 12 and 12'' and lattices 10 and 20. (MacGregor, column 4, lines 5-10).

The stent portion 16, 20 and 22 are depicted in Figs. 1 and 1A as being substantially straight members, i.e. having no segments of curvature along any longitudinal axis. The wires 24, 26 are substantially straight in the longitudinal direction except for a bend at the point of bifurcation. (MacGregor, column 4, lines 10-14; Fig. 1). Thus, as depicted in Fig. 1, the wires 24, 26 do not have turns that are distributed substantially equal along the length of the stent because the wires have only one bend at the point of bifurcation which is the point of curvature being cited by the Examiner. Further, MacGregor fails to describe that any of the loops 12,

12', 12" extend through the area of bifurcation. In other words, there is a discontinuity of the stent configuration at the area of bifurcation. (see e.g., MacGregor, Fig. 1A). The general depictions of Figs. 2A-3D, which schematically show the placement of the MacGregor stent within body vessels 50, 50a, 50b, depict portions of the stent being curved, but fail further detail the area of bifurcation, i.e., fails to show any wires and their turns being distributed substantially equally along the length of the device, including being distributed substantially equally and uniformly along the portion of curvature.

Thus, MacGregor fails to teach or suggest the claimed limitations because the wires 24, 26 only have one turn at the point of bifurcation and the turn is not therefore equally distributed along the length of the stent. Further, the stent coils 12, 12', 12'' are not equally distributed over the length of the stent due to discontinuity at the point of bifurcation.

Accordingly MacGregor fails to cure the deficiencies of Suh.

Thus, Suh and MacGregor, individually or in combination, fail to teach or suggest the present invention.

Therefore, reconsideration and withdrawal of the rejections of claims 12-14, 28, 29 and 30 under 35 U.S.C. §103(a) are respectfully requested.

Suh in view of Martin:

As discussed above, Suh fails to teach or suggest a stent scaffold having a segment of curvature where stent wires are substantially equally and uniformly distributed along the length of the segment of curvature of the stent to provide a constant pitch of wires therealong, and fails to teach or suggest a stent scaffold having a segment of curvature where stent wires are substantially equally and uniformly distributed along the length of the segment of curvature of the stent and where the wires have an increased pitch at the outside segment and have an reduced pitch at the inside segment when disposed on a straight mandrel. Further, Suh teaches away from the present invention as Suh specifically states that curvature of its stent is only

possible through unequal distribution of its stent wires in the curved state. (See Suh, column 4, lines 38-48 as presented above).

Martin, however, fails to cure the deficiencies of Suh. Martin is directed to prosthesis 1 having a graft 2 having a woven, stainless steel, self-expanding mesh support 3 bonded to the graft 2. (Martin, column 2, lines 49-57) (emphasis added). The prosthesis 1 is shown as being curved in both Figs. 1 and 4. Fig. 1 depicts details of the prosthesis 1, and Fig. 4 schematically depicts placement of the prosthesis in a hypogastric artery. (Martin, column 2, lines 34-43). In Fig. 1, Martin shows prosthesis 1 as having a large end 6 tapering down to a smaller end 6. Martin shows wire crossings at the large end 5, but fails to show any wire crossing details at the smaller end 6 or portions therebetween. The cited Martin reference must be considered for the entirety of its teachings. *Bausch & Lomb, Inc. v. Barnes-Hind, Inc.*, 230 U.S.P.Q. 416, 419 (Fed. Cir. 1986). It is impermissible during examination to pick and choose from a reference only so much that supports the alleged rejection. *Id.* Thus, the Examiner may not ignore the deficiencies of Martin which include, inter alia, no crossing details towards the tapered end 6 of the device.

Accordingly Martin fails to cure the deficiencies of Suh.

Thus, Suh and Martin, individually or in combination, fail to teach or suggest the present invention.

Therefore, reconsideration and withdrawal of the rejections of claims 18 and 34 under 35 U.S.C. §103(a) are respectfully requested.

Suh in view of Vardi:

As discussed above, Suh fails to teach or suggest a stent scaffold having a segment of curvature where stent wires are substantially equally and uniformly distributed along the length of the segment of curvature of the stent to provide a constant pitch of wires therealong, and fails to teach or suggest a stent scaffold having a segment of curvature where stent wires are

substantially equally and uniformly distributed along the length of the segment of curvature of the stent and where the wires have an increased pitch at the outside segment and have an reduced pitch at the inside segment when disposed on a straight mandrel. Further, Suh teaches away from the present invention as Suh specifically states that curvature of its stent is only possible through unequal distribution of its stent wires in the curved state. (See Suh, column 4, lines 38-48 as presented above).

Vardi, however, fails to cure the deficiencies of Suh. Vardi discloses that its stent portions are not distributed substantially equally along the length of a segment of curvature of the stent. For example, FIG. 5 clearly depicts a gradient of wire crossings throughout the portion of curvature of the depicted stent. Such a gradient or non-equal distribution of stent members is repeatedly shown through Vardi. (See, FIG 13c, FIG. 13d and FIG. 14b.

Accordingly Vardi fails to cure the deficiencies of Suh because Vardi fails to show an equal distribution of stent wires at and throughout areas of curvature of its stent.

Thus, Suh and Vardi, individually or in combination, fail to teach or suggest the present invention.

Therefore, reconsideration and withdrawal of the rejections of claims 19, 21, 35 and 37 under 35 U.S.C. §103(a) are respectfully requested.

Suh in view of Marin:

As discussed above, Suh fails to teach or suggest a stent scaffold having a segment of curvature where stent wires are substantially equally and uniformly distributed along the length of the segment of curvature of the stent to provide a constant pitch of wires therealong, and fails to teach or suggest a stent scaffold having a segment of curvature where stent wires are substantially equally and uniformly distributed along the length of the segment of curvature of the stent and where the wires have an increased pitch at the outside segment and have an reduced pitch at the inside segment when disposed on a straight mandrel. Further, Suh teaches

away from the present invention as Suh specifically states that curvature of its stent is only possible through unequal distribution of its stent wires in the curved state. (See Suh, column 4, lines 38-48 as presented above).

Marin, however, fails to cure the deficiencies of Suh. Marin describes a graft stent complex 44 L, R which has cephalic stents 48 and caudal stent 49 L, R disposed at opposing ends of knitted textile graft 45 L, R. (Marin, column 6, lines 35-40). In other words, the prosthesis of Marin is a knitted textile graft with stents disposed at the ends of the graft for securement purposes. Further, Marin teaches that the stents, which are secured only to the ends of the grafts, should not extend into the pathological defect, i.e., the curved aneurysm region, and should not extend into branched regions. (Marin, column 20, lines 46-40). Therefore, as noted by the Examiner, the graft 46 L, R has a segment of curvature. Marin, however, fails to teach or suggest a stent having such a curvature. Further, Marin fails to teach or suggest a prosthesis comprising a stent wire having turns that is equally distributed over the length of the prosthesis, including at least one curved segment of the prosthesis.

Moreover, Marin teaches that the stent portions of its prosthesis must not extend along the entire length of the prosthesis. Marin teaches that its stent portions must not traverse curved bodily regions, such as aneurysms, or branched regions. Accordingly, Marin fails to teach or suggest the present invention because its stent portions do not extend along the length of its device.

Thus, Martin fails to cure the deficiencies of Suh.

Therefore, reconsideration and withdrawal of the claim rejections are respectfully requested.

Conclusion

There is no teaching in the prior art of a curved stent having a segment of curvature where stent wires are substantially equally and uniformly distributed along the length of the segment of curvature of the stent to provide a constant pitch of wires therealong, or of a curved stent having a segment of curvature where stent wires are substantially equally and uniformly distributed along the length of the segment of curvature of the stent and where the wires have an increased pitch at the outside segment and have an reduced pitch at the inside segment when disposed on a straight mandrel. The invention cannot be properly arrived at through any combination of the references. Only through hindsight reconstruction of the references may one possibly arrive at the present invention. Any attempt at hindsight reconstruction, however, to arrive at the claim limitations of the subject invention is strictly prohibited. *In re Oetiker*, 24 U.S.P.Q.2d 1443, 1445-46 (Fed. Cir. 1993).

Moreover, the cited references must be considered for the entirety of their teachings. *Bausch & Lomb, Inc. v. Barnes-Hind, Inc.*, 230 U.S.P.Q. 416, 419 (Fed. Cir. 1986). It is impermissible during examination to pick and choose from a reference only so much that supports the alleged rejection. *Id.* Thus, the specific disclosure and teachings of Suh, Caro, MacGregor, Martin, Vardi and Marin that teach away from the present invention must be considered by the Examiner.

Thus, Suh, Caro, MacGregor, Martin, Vardi and Marin, individually or in combination, fail to disclose, teach or suggest the subject invention as presently defined by independent claims 1 and 23. Therefore, reconsideration and withdrawal of the claim rejections are respectfully requested.

Summary

Therefore, Applicant respectfully submits that independent claims 1 and 23, and all claims dependent therefrom, are patentably distinct. Further, Applicant respectfully requests

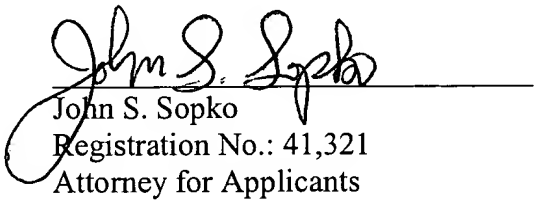
entry and allowance of withdrawn claim 41. This application is believed to be in condition for allowance. Favorable action thereon is therefore respectfully solicited.

Should the Examiner have any questions or comments concerning the above, the Examiner is respectfully invited to contact the undersigned attorney at the telephone number given below.

The Commissioner is also hereby authorized to charge payment of any additional fees associated with this communication, or credit any overpayment, to Deposit Account No. 08-2461. Such authorization includes authorization to charge fees for extensions of time, if any, under 37 C.F.R § 1.17 and also should be treated as a constructive petition for an extension of time in this reply or any future reply pursuant to 37 C.F.R. § 1.136.

Further, please kindly send all further correspondence relating to the subject application to the attorney of record at the address indicated below.

Respectfully submitted,



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